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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/711,408

09/16/2004

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12927-11 LAB

5407

7590

07/05/2006

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/711,408	FREITAG ET AL.	
	Examiner	Art Unit	
	Christopher L. Chin	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/20/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 11-13, 15, and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague because the claim is incomplete. While the preamble of the claim recites a method for determining the presence or absence of at least one analyte in a liquid sample, the body of the claim fails to recite any steps for the detection of analyte(s). The body of the claim only recites steps for providing an assay device and steps for contacting sample and reagent to the assay device. There is no step for detecting the labeled reagent and no correlation step that relates detected labeled reagent to the presence of analyte(s).

Claim 15 is vague as to where the absorbent sink is situated. Merely reciting the absorbent sink as being "on one of the components" does not clearly specify where the absorbent sink is situated on either of the components relative to the elements that comprise each of the components.

Claim 21 is vague because the claim is incomplete. While the preamble of the claim recites a method for determining the presence, absence, or quantity of at least one analyte in a liquid sample, the body of the claim fails to recite any steps for the detection or quantitation of analyte(s). The body of the claim only recites steps for providing an assay device and steps for contacting sample and reagent to the assay

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device. There is no step for detecting the labeled reagent and no correlation step that relates detected labeled reagent to the presence or quantity of analyte(s).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4-6, 9-15, 18, 19, 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark.

Clark (US Patent 5,726,010) discloses a bi-directional chromatographic assay device for performing specific binding assays on fluid samples suspected of containing analyte molecules. Generally, to perform such assays using the disclosed device a sample containing the analyte is applied to the device via a sample application means and allowed to flow along the flow matrix of the device. Analyte binds to immobilized analyte specific reagent in a detection zone on the flow matrix. The flow matrix is then brought into contact with one or more reagent reservoirs, which are separated from the flow matrix until use of the device, that contain a labeled detection reagent and an absorbent reservoir. Contact with the absorbent reservoir reverses the direction of fluid flow to bring the labeled reagent into contact with the detection zone (col. 6, lines 17-67

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and Figs 2A and 2B). The device may be placed in a kit along with all the necessary reagents for carrying out the desired assays (col. 12, lines 10-25).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 3, 7, 8, 16, 17, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of May et al.

See above for the teachings of Clark.

Clark differs from the instant invention in failing to teach use of colloidal gold particles as a label reagent and detection of hCG.

May et al (WO 88/08534) discloses a chromatographic test strip device for performing immunoassays. The device can be used for the detection of hCG with the appropriate antibody reagents (see page 7). Label reagents that can be used in the device include colloidal gold (see page 10).

It would have been obvious to one of ordinary skill in the art to use colloidal gold as a label reagent, as taught by May et al, in the device of Clark because May et al shows it to be conventional in the art to use colloidal gold as label reagents in chromatographic test strip devices such as those disclosed in Clark and May et al.

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Furthermore, colloidal gold obviates the need for additional reagents such as substrates for the enzyme labels taught by Clark.

With respect to the detection of hCG, it would have been obvious to one of ordinary skill in the art to detect hCG in the device of Clark because Clark is not limiting in regard to the analytes that can be detected in the disclosed device and May et al shows that hCG can be detected on test strips devices such as the device of Clark, given the appropriate antibody reagents.

6. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Foster et al.

See above for the teachings of Clark.

Clark differs from the instant invention in failing to teach a kit with instructions.

Foster et al (US Patent 4,444,879) discloses a test kit for performing immunoassays that includes instructions (see Figure 6).

It would have been obvious to one of ordinary skill in the art to include instructions, as taught by Foster et al, in the kit of Clark to insure that the assays using the device of Clark are performed in the correct manner.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher L. Chin
Primary Examiner
Art Unit 1641

6/23/06